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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,751	HUNTER ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-45,49,56-59 and 61-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63* is/are allowed.

6)☒ Claim(s) *43-45,49,56-59,61,62 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2004 has been entered.

[2] Claims 43-45, 49, 56-59, and 61-64 are pending in the application.

[3] Applicants' amendment to the claims, filed March 22, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims in the instant application.

[4] Applicant's arguments filed March 22, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Priority

[6] It is noted that applicants claim priority to application PCT/US97/05959. However, the sequence of $Pfsp_{155}$ (SEQ ID NO:62) of the instant application is not

supported by application PCT/US97/05959 as $Pfsp_{155}$ of application PCT/US97/05959 (corresponding to SEQ ID NO:62; see page 24, lines 10-11 of WO 97/37676) is not identical to $Pfsp_{155}$ (SEQ ID NO:62) of the instant application (See Appendix A).

Specification/Informalities

[7] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "*Ctenocephalides felis* Saliva Protein."

Claim Objections

[8] Claim 57 is objected to as being grammatically incorrect in the recitation of "the protein is produce recombinantly." It is suggested that, for example, applicants replace "the protein is produce recombinantly" with "the protein is produced recombinantly."

[9] Claim 61 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 43. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, Second Paragraph

[10] Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 is indefinite in the recitation of "$fspl_{155}$". While the specification defines "$Pfspl_{155}$" as referring to the protein of SEQ ID NO:62 (see pages 24 and 94 of the instant specification) and has been interpreted accordingly, the examiner can find no definition for the term "$fspl_{155}$". It is suggested that applicants clarify the meaning of the term.

Claim Rejections - 35 USC § 112, First Paragraph

[11] Claim(s) 43-45, 49, 56-59, 61-62, and 64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 43, 61 (claims 44-45, 49, 56-59, and 62 dependent therefrom), and 64 recite the limitation "at least 38 contiguous amino acids." The examiner can find no support for this limitation in the claims, specification, or drawings as originally filed. Applicants argue that support for this limitation can be found in US Patent 5,795,862 to which the instant application claims priority, by disclosing SEQ ID NO:6, which represents the N-terminal 38 amino acids of Pfspl. However, applicants' assertion that the instant application claims priority to US Patent 5,795,862 (corresponding to US non-provisional application 08/487,001) is inconsistent with the

priority data provided by applicants in the amendment to the specification in the transmittal letter filed February 07, 2002. The instant application is a divisional of application 09/171,156, which issued as US Patent 6,368,846, which is a national stage of PCT/US97/05959, which is a continuation of application 08/630,822, which issued as US Patent 5,840,695. The examiner can find no priority claim to application 08/487,001 or US Patent 5,795,862. Even if the instant application properly claims priority to US Patent 5,795,862, it is noted that the disclosure of SEQ ID NO:6 in US Patent 5,795,862 fails to provide support for the recited limitation of "at least 38 contiguous amino acids" because the 38 contiguous amino acids as recited in the instant claims are not limited to those amino acids of SEQ ID NO:6, but encompass any 38 contiguous amino acids of SEQ ID NO:62. In the event that the examiner has inadvertently overlooked support for this limitation in the instant application or to those applications to which priority is claimed, the examiner requests that applicants direct the examiner's attention to such support.

[12] Claim(s) 43-45, 57-58, and 61-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 43 and 61 (claim 58 dependent therefrom) are drawn to an isolated protein comprising at least 38 contiguous amino acids of SEQ ID NO:62. Claims 44-45 limit the protein of claims 61 to a Ctenocephalides or a Ctenocephalides felis protein.

Claim 57 limits the protein of claim 61 to being produced recombinantly. Claim 62 limits the protein of claim 61 to a flea saliva protein.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single species of the genus of claimed proteins, i.e., SEQ ID NO:62. The specification fails to describe any additional representative species of the claimed genus, which encompasses species that are widely variant in both structure and function, including (but not limited to) any polypeptide having any biological activity including non-functional polypeptides. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". As

such, the disclosure of the single representative species of SEQ ID NO:62 is insufficient to be representative of the attributes and features of *all* species encompassed by the recited genus of peptides. Given the lack of description of a representative number of proteins, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Furthermore, regarding the genus of proteins of claims 44-45, 57, and 62, it is noted that the genus is limited to those proteins that are Ctenocephalides or Ctenocephalides felis proteins (claims 44-45), recombinantly produced proteins (claim 57), and flea saliva proteins (claim 62). MPEP § 2163 states (citing *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021), "A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials". In this case, the specification fails to provide those characteristics that distinguish the claimed subgenus of Ctenocephalides or Ctenocephalides felis proteins, recombinantly produced proteins, or flea saliva proteins from the larger genus of proteins that are not Ctenocephalides or Ctenocephalides felis proteins, recombinantly produced proteins, or flea saliva proteins. For the reasons stated above, the specification fails to provide adequate written description for the claimed genus of isolated proteins.

[13] Response to Arguments: Applicants argue the claims have been amended to require that the claimed protein comprise at least 38 contiguous amino acids of SEQ ID NO:62, it is a simple matter to view SEQ ID NO:62 and select 38 contiguous amino

acids, and that a skilled artisan has all the information necessary to make a protein within the scope of the claims. Applicants' argument is not found persuasive.

It is noted that applicants' arguments are not commensurate in scope with the claimed invention. In this case, the genus of claimed proteins is not limited to at least 38 contiguous amino acids of SEQ ID NO:62. Instead, the genus encompasses all species that comprise at least 38 contiguous amino acids of SEQ ID NO:62. It should be noted that claim 61 has been interpreted as a protein comprising at least 38 contiguous amino acids in accordance with MPEP 2111, which directs the examiner to provide claims their broadest reasonable interpretation.

Regarding claims reciting "comprising" as a transitional phrase, applicants argue that it is irrelevant what sequences lie outside of the selected 38 contiguous amino acids asserting that as long as the protein comprises 38 contiguous amino acids that are identical to 38 contiguous amino acids of SEQ ID NO:62, the protein falls within the scope of the claims. Applicants' argument is not found persuasive.

Contrary to applicants' assertion, the sequence that is outside of the "selected 38 contiguous amino acids" of SEQ ID NO:62 is highly relevant as it is a critical feature of the claimed invention. MPEP 2163 states:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (e.g., promoters, enhancers, coding regions, and other regulatory elements) which are also included.

Similar to the example provided above, the claims encompass species that share the structural characteristic of having at least 38 contiguous amino acids of SEQ ID NO:62, with additional structures i.e., amino acid sequence flanking the at least 38 contiguous amino acids of SEQ ID NO:62, that is also included in the claim. In this case the sequence flanking the 38 contiguous amino acids of SEQ ID NO:62 is a critical feature of the claimed invention, which has not been described in the specification, and thus, the genus of claimed proteins lacks adequate written description. The full sequence of the polypeptide – not just the 38 contiguous amino acids of SEQ ID NO:62 – must be considered to determine whether the polypeptide is adequately described by the instant specification. In this case, the disclosure of the single species of SEQ ID NO:62 fails to represent all polypeptides encompassed by the genus.

Applicants argue that more than a single species of the genus of claimed proteins is disclosed in the specification as priority document US Patent 5,795,862 discloses SEQ ID NO:25 and 35, which include 38 contiguous amino acids that are identical to 38 contiguous amino acids of SEQ ID NO:62, and therefore fall within the scope of the claims. In support of their argument, applicants provide an alignment showing that amino acids 11-48 of SEQ ID NO:62 are present in SEQ ID NO:25 and 35. Applicants' argument is not found persuasive.

It is noted that applicants' assertion that the instant application claims priority to application 08/487,001, issued as US Patent 5,795,862, is inconsistent with the priority data provided by applicants in the amendment to the specification in the transmittal letter filed February 07, 2002. The instant application is a divisional of application

09/171,156, which issued as US Patent 6,368,846, which is a national stage of PCT/US97/05959, which is a continuation of application 08/630,822, which issued as US Patent 5,840,695. The examiner can find no priority claim to application 08/487,001. Even if the instant application claims priority to application 08/487,001, it is noted that the additional species of SEQ ID NO:25 and 35 of application 08/487,001 fail to represent the genus of claimed proteins. It is also noted that the claims do not require that the genus of proteins comprise only amino acids 11-48 of SEQ ID NO:62, but any 38 contiguous amino acids of SEQ ID NO:62. Even if the genus of claimed proteins was limited to those that comprise amino acids 11-48 of SEQ ID NO:62, the specification fails to describe even this limited genus. A representative number of species may be defined by recitation of structural features which are common to members of the genus and constitute a substantial portion of the genus (see University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (1997)). While all species encompassed by the genus of claimed proteins require at least 38 contiguous amino acids of SEQ ID NO:62, this structural feature is insufficient to describe all species of the genus as this structural feature does not constitute a substantial portion of the protein of SEQ ID NO:62, which has 155 amino acids.

[14] Claims 43-45, 57-58, and 61-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein of SEQ ID NO:62, does not reasonably provide enablement for the broad scope of claimed proteins and compositions thereof. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass all proteins comprising at least 38 contiguous amino acids of SEQ ID NO:32 and having any biological activity and a composition thereof. The broad scope of claimed proteins and compositions thereof is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims. In this case the disclosure is limited to the protein of SEQ ID NO:62.

- The lack of guidance and working examples: The specification provides only a single working example of the claimed protein, i.e., SEQ ID NO:62. This working

example fails to provide the necessary guidance for making and/or using the entire scope of claimed proteins. The specification fails to provide guidance regarding those amino acids of SEQ ID NO:62 that may be altered by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired activity. Furthermore, the specification fails to provide guidance as to how to use those variant proteins having activities other than the desired activity, e.g., non-functional polypeptides or polypeptides having activity other than SEQ ID NO:62.

- The high level of unpredictability in the art: The amino acid sequence of a protein determines the protein's structural and functional properties. Predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained in detail above. Thus, a skilled artisan would recognize the high degree of unpredictability that the entire scope of polynucleotides would encode a polypeptide having the desired

activity. Furthermore, it is noted that the protein of SEQ ID NO:62 is to be used as an antigen for the production of antibodies. The ability of an antibody to bind a particular epitope within a polypeptide is dependent upon the amino acid sequence of the polypeptide, and, if the polypeptide is in its native state, i.e., non-denatured, the conformation acquired by the amino acid sequence. See Abaza et al. *J Protein Chem* 11:433-444 who teach that "the reaction of a protein antigen with its antibodies is influenced by conformational changes" (page 436, left column, bottom to right column, top)). It is highly unpredictable as to which alterations in a protein's amino acid sequence can be made with an expectation of maintaining the ability of an antibody to bind the altered polypeptide sequence.

- The state of the prior art supports the high level of unpredictability: The state of the art provides evidence for the high degree of unpredictability in altering a protein sequence with an expectation that the protein will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). While it is acknowledged that this reference was published in 1991, to date there is no method for reasonably predicting the effects of even a *single* amino acid mutation on a protein. Also, it is noted that the protein is to be used as an antigen in the

production of an antibody. The state of the art provides evidence for the high degree of unpredictability that an antibody, e.g., an antibody that binds SEQ ID NO:62, will bind to an altered polypeptide sequence, e.g., variants of SEQ ID NO:62. For example, Colman et al. (*Res Immun* 145:33-36) teach that "[s]ingle amino acid changes within the interface of an antibody-antigen complex... ...can effectively abolish the interaction entirely" (page 33, right column). Furthermore, Abaza et al. (*J Protein Chem* 11:433-444) teach that alterations outside of the boundaries of an antigenic site can significantly affect antibody binding (page 443, right column to page 444, left column).

- The amount of experimentation required is undue: While methods of generating variants of a given protein, e.g., site-directed mutagenesis, are known, it is not routine in the art to screen for all proteins having a substantial number of modifications having any function, as encompassed by the instant claims. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

[15] Response to Arguments: Applicants argue the claims have been amended to remove the binding requirement so no experimentation would be required to make the instant invention. Applicants argue SEQ ID NO:62 is disclosed, thereby enabling a skilled artisan to make proteins comprising 38 contiguous amino acids. Applicants' argument is not found persuasive.

There is no dispute that the sequence of SEQ ID NO:62 is disclosed in the specification. However, based upon the Factors of In re Wands as described in detail above, it is the examiner's position that undue experimentation is required for a skilled artisan to make and/or use the full scope of claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

[16] Claims 43-45, 57-58, and 61-62 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,795,862 (hereafter referred to as the "'862 Patent"). Claims 43, 57-58, and 61 are drawn to an isolated protein comprising at least 38 contiguous amino acids of SEQ ID NO:62 and a composition thereof. Claims 44-45, 57, and 62 limit

the protein to a Ctenocephalides or Ctenocephalides felis protein, a recombinantly produced protein, or a flea saliva protein.

The '862 Patent teaches the polypeptides of SEQ ID NO:25 and 35, which comprise at least 38 contiguous amino acids of SEQ ID NO:62 of the instant application (see Appendix B). The '862 Patent teaches that the proteins of SEQ ID NO:25 and 35 were isolated from Ctenocephalides felis flea saliva extract (see Examples 1-2) and further teaches the recombinant production of SEQ ID NO:25 and 35 (Example 11). This anticipates claims 43-45, 57-58, and 61-62 as written.

[17] Claims 43-45, 57-58, and 61-62 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,646,115 (the '115 Patent). Claims 43, 57-58, and 61 are drawn to an isolated protein comprising at least 38 contiguous amino acids of SEQ ID NO:62 and a composition thereof. Claims 44-45, 57, and 62 limit the protein to a Ctenocephalides or Ctenocephalides felis protein, a recombinantly produced protein, or a flea saliva protein.

The '115 Patent teaches the polypeptide of SEQ ID NO:25, which comprises at least 38 contiguous amino acids of SEQ ID NO:62 of the instant application (see Appendix C). The '115 Patent teaches that the protein of SEQ ID NO:25 was isolated from Ctenocephalides felis flea saliva extract (see Examples 1-2) and further teach recombinant production of their protein (column 6, lines 48-49). This anticipates claims 43-45, 57-58, and 61-62 as written.

Claim Rejections – Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[18] Claim 58 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of US Patent 5,795,862 ('862 Patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 58 is generic to claim1 (reciting fspl, which refers to SEQ ID NO:25, see column 10, lines 60-62 of the '862 Patent) and claim 2 (reciting SEQ ID NO:25 or 35) of the '862 Patent. That is, claim 1 (reciting fspl) and claim 2 (reciting SEQ ID NO:25 or 35) of the '862 Patent falls entirely within the scope of claim 58 or, in other words, claim 58 is anticipated by claim 1 (reciting fspl) and claim 2

(reciting SEQ ID NO:25 or 35) of the '862 Patent. SEQ ID NO:25 (fspl) and 35 of the '862 Patent comprise at least 38 contiguous amino acids of SEQ ID NO:62 (see Appendix B).

[19] Claims 58 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of US Patent 5,646,115 ('115 Patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 58 is generic to claim 1 (reciting fspl, which refers to SEQ ID NO:25, see column 10, lines 40-42 of the '115 Patent) of the '115 Patent and claim 62 is generic to claim 4 (reciting SEQ ID NO:25) of the '115 Patent. That is, claim 1 (reciting fspl) and claim 4 (reciting SEQ ID NO:25) of the '115 Patent falls entirely within the scope of claims 58 and 62, respectively, or, in other words, claim 58 is anticipated by claim 1 (reciting fspl) of the '115 Patent and claim 62 is anticipated by claim 4 (reciting SEQ ID NO:25) of the '115 Patent. SEQ ID NO:25 (fspl) of the '115 Patent comprises at least 38 contiguous amino acids of SEQ ID NO:62 (see Appendix C).

[20] Claim 58 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 20-21 of US non-provisional application 10/271,344 ('344 Application). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 58 is generic to claim 14 (reciting SEQ ID NO:25 or 35) and claims 20-21 (reciting fspl, which refers to SEQ ID NO:25, see page 6, left column of the '344 Application) of the '344 Application. That is, claim 14 (reciting SEQ ID NO:25 or 35) and claims 20-21 (reciting fspl) of the '344 Application fall entirely within the scope of claim 58 or, in other words, claim 58 is anticipated by claim 14 (reciting SEQ ID NO:25 or 35) and claims 20-21 (reciting fspl) of the '344 Application. SEQ ID NO:25 (fspl) and 35 of the '344 Application comprise at least 38 contiguous amino acids of SEQ ID NO:62 (see Appendix D). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

[21] Status of the claims:

- Claims 43-45, 49, 56-59, and 61-64 are pending.
- Claims 43-45, 49, 56-59, 61-62, and 64 are rejected.
- Claim 63 is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652
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